REMARKS

Claims 7 and 9-20 are pending in the application. Claims 11 and 12 have been cancelled. Claim 14 has been withdrawn from consideration. Claims 7, 9, 10, 12, 13 and 15-20 stand rejected. Claims 7 and 13 have been amended. Reconsideration and allowance of Claims 7, 9, 10, 13, and 15-20 is respectfully requested.

The Rejection of Claims 7, 9, 10, 12, 13 and 15-20 on the Ground of Non-Statutory Obviousness-type Double Patenting as Being Unpatentable Over Claims 1-4 of U.S. Patent No. 6,734,172

Applicants will file a terminal disclaimer in compliance with 37 C.F.R. 3.373(b) upon the allowance of claimed subject matter in the instant application.

The Rejection of Claims 7, 9, 10, 12, 13 and 15-20 Under 35 U.S.C. §112, First Paragraph (Enablement)

Claims 7, 9, 10, 12, 13 and 15-20 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement. The Examiner acknowledges that the specification is enabling for a vaccine composition for eliciting or increasing the titer of antibodies for Her2/Neu protein, wherein the vaccine composition comprises one or more individual expression constructs encoding Her2/Neu, CD86/B7.2 and 4-1BB ligand, and either CD86/B7.2 or CD80/B7.1. However, the Examiner has taken the view that the specification does not reasonably provide enablement for other vaccine compositions for eliciting or increasing the titer of antibodies for any cell surface receptor antigen, wherein the vaccine composition comprises one or more recombinant expression constructs encoding any cell surface receptor antigen plus any immune response altering molecule in combination with 4-1BB ligand.

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

While not acquiescing with the Examiner's position, but in order to facilitate prosecution, Claim 7 has been amended to recite "wherein the cell surface receptor antigen is selected from the group consisting of HER1, HER2, HER3 and HER4." Claim 13 which depends from Claim 7 has been amended to recite "wherein the cell surface receptor antigen is HER2."

As acknowledged by the Examiner, the specification discloses that combinations including either B7.1 or B7.2 were effective for increasing the titer of antibodies for the cell surface receptor antigen.

It is also noted that the Examiner has mischaracterized the claims as being drawn to the use of any immune response altering molecule in combination with 4-1BB ligand. Rather, it is noted that independent Claim 7, from which Claims 9, 10, 12, 13 and 15-20 depend, recites "wherein said first immune response molecule is 4-1BB ligand and said second immune response altering molecule is selected from the group consisting of CD80/B7.1 and CD86/B7.2."

It is submitted that the specification enables the full scope of the claims, as amended. As acknowledged by the Examiner, the specification is enabling for a vaccine composition for eliciting or increasing the titer of antibodies for HER2/Neu protein, wherein the vaccine composition comprises one or more individual expression constructs encoding Her2/Neu, CD86/B7.2 and 4-1BB ligand, and either CD86/B7.2 or CD80/B7.1. As known by those of skill in the art, HER-1, HER-2, HER-3 and HER-4 are all members of the epidermal growth factor receptor family of receptor tyrosine kinases and share the fundamental structural features of this family of transmembrane proteins. Therefore, the results demonstrated with the compositions of the instant invention using the HER2/Neu antigen would be expected to be representative of HER-1, HER-3, and HER-4, as claimed.

With regard to the Examiner's assertions that applicants' own examples demonstrate the unpredictability in the art of DNA vaccines, it is noted that the Examiner has relied on the

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

observation that Group 4 mice, (immunized with pLNCX-Rat-Neu + pLNCX-B7.2) exhibited an increase in tumor size, which is not relevant to the claimed invention. Rather, contrary to the Examiner's assertion, the claimed invention is directed to a composition comprising the *combination* of a first vector encoding a cell surface receptor antigen, *a second vector encoding the 4-1BB ligand and* at least one of B7.1 or B7.2. This claimed combination is demonstrated to generate increased antibody titer to the cell surface receptor antigen, as described above.

Therefore, based on the guidance provided in the specification, in view of the knowledge in the art, one skilled in the art would be able to make and use the claimed compositions, which is sufficient to satisfy the enablement requirement. M.P.E.P. Section 2164.01(c). Accordingly, removal of this ground of rejection is respectfully requested.

The Rejection of Claims 7, 9, 10, 12, 13 and 15-20 Under 35 U.S.C. § 112, Second Paragraph (Indefiniteness)

Claims 7, 9, 10, 12, 13 and 15-20 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In particular, the Examiner has taken the view that the term "increasing" is unclear because the specification does not provide a standard for ascertaining the requisite degree.

While not acquiescing to the Examiner's position, but in order to facilitate prosecution, the preamble of Claim 7 has been amended to delete the phrase "or increasing the titer of antibodies." Accordingly, removal of this ground of rejection is respectfully requested.

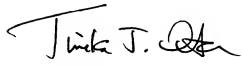
LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

CONCLUSION

In view of the foregoing remarks, applicants submit that all of the pending claims are in condition for allowance and notification to this effect is respectfully submitted.

Respectfully submitted,

CHRISTENSEN O'CONNOR
JOHNSON KINDNESS PLLC



Tineka J. Quinton
Registration No. 53,496
Direct Dial No. 206.695.1655

TJQskg

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100